REMARKS

In the Office Action sent on December 19, 2007, the Examiner withdrew the finality of the previous Office Action in response to the Applicants' Request for Continued Examination under 37 CFR 1.114, but maintained the rejections and extended those rejections to new claims 30-40. The Examiner also maintained rejections for nonstatutory obviousness-type double patenting and extended those rejections to new claims 30-40. Finally, the Examiner rejected new claim 29 as obvious under 35 USC §103(a) and for nonstatutory obviousness-type double patenting. Each rejection is addressed separately below. In view of the above amendments, the 37 CFR 1.132 declarations submitted with this response and with the response dated April 24, 2007, and the remarks set forth below, Applicants respectfully ask the Examiner to reconsider the merits of this patent application.

Applicants hereby petition for a two-month extension of time under 37 CFR § 1.136 to make this response timely. A small entity fee under 37 CFR 1.17(a)(2) of $230 is believed due. Please charge this fee to Deposit Account No. 17-0055.

No additional extension of time is believed to be required at this time; however, if an additional extension of time is required in this or any subsequent response, please consider this a petition for any needed extension of time and a request to charge the petition fee to Deposit Account No. 17-0055.

I. CLAIM AMENDMENTS

Claims 27 and 40 are amended to recite that body weight uniformity is measured not merely passively observed. Support for these new amendments is found in paragraph [0018] of the specification.

II. REJECTIONS UNDER 35 U.S.C. § 102(B) OVER U.S. PATENT NO. 6,213, 930 AND U.S. PATENT NO. 6,383,485

A. The Examiner's rejections.

The Examiner rejected claims 1, 5-10, 12, 25, 27, and 30-40 as anticipated by U.S. Patent No. 6,213, 930 and by U.S. Patent No. 6,383,485, alleging that the methods taught by the cited patents would inherently achieve undisclosed improvements in body weight uniformity because

the patents disclose the same method steps as the rejected claims. The Examiner also maintained that dosage ranges cannot distinguish the pending claims because neither the pending claims nor the claims of the cited patents recite any specific dosage limitations. The Examiner also stated that data in the specification refuted Applicants' argument that the dosages disclosed in the cited patents are insufficient to decrease body weight uniformity or to reduce the coefficient of variation by at least 0.5 or 0.8, as claimed. Specifically, the Examiner asserted that data in Table 1 indicate that the dosage disclosed in the cited patents reduces CV and improves body weight uniformity. Finally, the Examiner asserted that the step of observing an improvement in body weight uniformity is not a patentable limitation, because observing is a necessary part of the claimed process, and because observation of an inherent property does not impart patentability. Applicants respond to each argument below.

B. The cited patents do not anticipate Applicants' claims because the dosage ranges there disclosed are insufficient to achieve the effect of the claimed methods.

The cited patents do not anticipate the pending claims because the dosage range there disclosed is not an "amount sufficient to improve body weight uniformity" as recited in claim 1.

1. The dosage range disclosed in the cited patents is 0.0-0.5 g dietary dried egg yolk (containing anti-PLA_2 antibodies) per kg feed.

A patented invention's acceptable range limitations are those that one skilled in the art would recognize as being supported by the original disclosure. *See* MPEP § 2163.05(III). For example, in *In re Wertheim*, an inventor disclosed a concentration for a coffee extract of between 25 and 60 % solid matter, with specific examples containing 36 % and 50 % solid matter. 541 F.2d 257, 262 (C.C.P.A. 1976). The court held that claimed ranges are proper only if one skilled in the art would recognize from the disclosure that the invented process included those ranges. *Id.*

Thus a claim range of "at least 35% solids" was improper, because it embraced inventions containing solid content above the highest solid matter concentration (60%) disclosed in the specification. *Id.* at 263. Because concentrations above 60 % are outside the scope of the description, one skilled in the art would not recognize such a claim as being part of the invention. *Id.*

U.S. Patent Nos. 6,213, 930 and U.S. Patent No. 6,383,485 disclose only 0.0-0.5 g dietary dried egg yolk (containing anti-PLA_2 antibodies) per kg feed (0% to 0.05% by weight). See column 4, the first paragraph under "EXAMPLE" of both said U.S. patents. Accordingly, only this dosage range is (1) properly supported by the specification, and (2) disclosed for purposes of an anticipation analysis.

2. The supported and disclosed dosage range of 0.0-0.5 g/kg dietary dried antibody-containing egg yolk disclosed in the cited patents is not a dosage "sufficient to increase body weight uniformity" as claimed, because Table 1 shows that such dosages do not support a statistically significant increase in body weight uniformity.

While pending claims 1, 30 and 31 recite no specific numerical dosages, the suitable dosage in all claims is an amount sufficient to improve body weight uniformity in general or by at least a specific amount. A statistical analysis of the Table 1 data shows that the maximum dosage disclosed in the cited patents is not an amount "sufficient to improve body weight uniformity" as required in amended claim 1, let alone an amount sufficient to increase the coefficient of variation by at least 0.5 or 0.8, as required in claims 30 and 31. Accordingly, that dosage is not "sufficient to increase body weight uniformity," and the cited patents cannot anticipate the dosages recited by the pending claims.

It is well-known that a treatment is "sufficient" to produce a specific improvement only where the treatment, rather than chance variation or placebo effect, causes improvement in an experimental group relative to a control group. Accordingly, one skilled in the art would say that only dosages that produce statistically significant improvement in body weight uniformity would be sufficient to improve body weight uniformity. On the other hand, it is insufficient to merely observe the desired result in an experimental group compared to a control group in one or more selected trials because such variation could be the result of chance rather than the treatment.

Inventor Mingder Yang discussed his statistical analysis of the combined data of Fig. 1 in a Declaration filed under 37 CFR 1.132 with the response of April 24, 2007. He there analyzed the nine trials undertaken using a dosage of 0.5g/kg or less. Based on those trials, he found that such dosages do not improve body weight uniformity by a statistically significant amount. Now, in response to the Examiner's arguments regarding body weight uniformity improvements in the

trials using a dosage of exactly 0.5 g/kg, Inventor Yang undertook a similar statistical analysis of the six trials employing a dosage of 0.5 g/kg. Once again he found no statistically significant improvement in body weight uniformity. Yang presents this analysis in a second Declaration filed under 37 CFR 1.132 with this response.

3. In asserting that a dosage of 0.5 g/kg is an amount effective to increase body weight uniformity, the Examiner misinterpreted the data and used it in a way that one skilled in the art would not accept.

Using selective comparisons from individual trial data in Table 1, the Examiner argued that practice of the methods of the cited patents using a dosage of 0.5 g/kg anticipates the pending claims because the dosage is sufficient to improve body weight uniformity and sufficient to decrease the coefficient of variation by at least 0.5 or 0.8. Specifically, the Examiner asserted that trials 2-5 indicate that 0.5 g/kg improves body weight uniformity. OA at 4. The Examiner also asserted that the same dosage lowers the coefficient of variation by at least 0.8 (and also by at least 0.5) because the data in those four trials each show decrease of greater than 0.8 in the coefficient of variation. OA at 4.

This faulty conclusion arises because the Examiner ignored the trials that did not support his position, a faulty methodology that one skilled in the art would not accept because variations in body weight uniformity can be due to random or non-random factors other than the treatment given. Instead, one skilled in the art would apply statistical methods to the data as a whole to determine effectiveness of a particular dosage for increasing body weight uniformity or decreasing the coefficient of variation relative to control groups. Moreover, one skilled in the art would only conclude that a particular dosage or dosage range was effective only if the variations in the data as a whole were determined to be statistically significant (i.e., probably due to the treatment not chance).

In fact, while four trials carried out at a dosage of 0.5 g/kg showed improved body weight uniformity, two ignored trials carried out at a dosage of 0.5 g/kg showed decreased body weight uniformity (see trial 6 reporting an increase in the coefficient of variation from 20.63 to 22.39 and an increase in the coefficient of variation from 20.63 to 29.85). Still further, the Examiner ignored all three trials carried out at a dosage of less than 0.5 g/kg, two of which showed a decrease in body weight uniformity (see trial 7 reporting an increase in the coefficient of

variation from 7.51 to 11.148 and trial 9 reporting an increase in the coefficient of variation from 5.255 to 6.75).

In the Declarations submitted with this response and with the response of April 24, 2007, Inventor Yang analyzed the data in the specification and determined (1) no statistical significance in any increase in body weight uniformity in the nine trials using a dosage of 0.5g/kg or less, and (2) no statistical significance in any increase in body weight uniformity in the six trials using a dosage of 0.5g/kg. Thus, while some individual trials in the dosage range of the cited patents may show an increase in body weight uniformity, the data as a whole do not show that dosages in that range are effective for increasing body weight uniformity. Because such dosages are insufficient to increase body weight uniformity, they are necessarily outside the scope of the pending claims. Accordingly, the cited patents cannot anticipate the pending claims.

C. Because the dosage range of the cited patents is insufficient to improve body weight uniformity, improved body weight uniformity is not an inherent outcome of the methods of the cited patents.

The Examiner asserted that the methods of the cited patents would inherently achieve improved body weight uniformity. Because the dosages disclosed in the cited patents are insufficient to improve body weight uniformity, the Applicants respectfully disagree. The pending claims are not inherently anticipated by the cited patents.

As discussed in section 2 above, dosages in the range disclosed in the cited patents are insufficient to increase body weight uniformity. The nine Table 1 trials are almost evenly split between increases and decreases in body weight uniformity (5 to 4), and any observed increases in body weight uniformity at those dosages are not statistically significant. Thus, an improvement in body weight uniformity is not inherent in practicing the disclosed method. Instead, the improvement is only established at dosages higher than those disclosed in the cited patents.

D. Claims 27 and 40 are patentably distinct from the other claims because the claims recite the active step of measuring body weight uniformity in a target group of animals.

Amended claims 27 and 40 recite the step of measuring body weight uniformity in a group of target animals, rather than observing an improvement in body weight uniformity. The

amended claims recite an active process, and cannot be interpreted as merely reciting a passive observation of an inherent property. Paragraph [0018] of the specification discloses several methods for measuring body weight uniformity in a group of target animals. Each requires data collection and calculation, not simply passive observation. Thus as amended, one practicing the method of the cited patents would not automatically undertake the recited measuring step, nor does the practitioner simply recognize an inherent result of the method.

For the reasons outlined above, the cited patents cannot anticipate the pending claims. Applicants respectfully ask the Examiner to reconsider the anticipation rejections.

III. OBVIOUSNESS REJECTIONS UNDER 35 U.S.C. § 103 OVER U.S. PATENT NO. 6,213, 930 AND U.S. PATENT NO. 6,383,485 IN VIEW OF PIMENTEL

A. The Examiner's rejections.

The Examiner rejected claim 29 as obvious both over either U.S. Patent No. 6,213, 930 or U.S. Patent No. 6,383,485, each in view of Pimentel. Pimentel teaches that eggs and the antibodies present in dried egg powder are generally recognized as safe in feed additives, and teaches that yolk antibodies can be administered at various concentrations to improve health, body weight gain, and feed conversion efficiency. The Examiner asserted that in light of Pimentel, it would have been obvious to extend the dosage disclosed in the cited patents to other dosages shown to be safe and effective. Claim 29 recites a dosage of 0.6 to 2.4 g/kg dried antibody-containing egg yolk, which dosage is outside the range disclosed in the cited patents.

Citing *In re Aller,* the Examiner asserted that where the general conditions of a claim are disclosed in the cited patents, discovering the optimal range is routine or obvious. The Examiner stated that the dosages disclosed in the cited patents achieve improvements in body weight uniformity, and that changing the dosage to optimize results would be obvious. OA at 8.

B. Because the dosage range disclosed in the cited patents is ineffective for improving body weight uniformity, (1) the claim 29 dosages produce unexpected results, and (2) the skilled person finds no motivation to combine the cited patents.

A showing of either unexpected results or lack of suggestion to combine citations can overcome an obviousness rejection. *See* MPEP § 2145. As above, one skilled in the art would

have had no reason to practice either cited patent to increase body weight uniformity, and would have had no expectation that the methods would increase body weight uniformity, because the dosages of the cited patents are demonstrated above to be insufficient to increase body weight uniformity. Pimental is not to the contrary. Pimentel's disclosure of the safety of higher dosages says nothing about whether such higher dosages would improve body weight uniformity.

In re Aller involved different temperature and concentration ranges for a claimed process that could occur at either the claimed temperature and concentration range or the temperature and concentration range disclosed in the cited patents. The difference in *Aller* was truly about optimizing a known process. *See* MPEP § 2144.05(II)(A). In contrast, the dosage range disclosed in the patents cited here by the Examiner has not been shown to be effective at all. Indeed, Applicants have shown that the dosage range is ineffective.

Concentration differences can support patentability where evidence indicates that the newly claimed but previously undisclosed concentration is critical to the invention. *See* MPEP § 2144.05(II)(A) and (III). Here, the dosages disclosed in the cited patents are not effective for increasing body weight uniformity, while the dosages recited in the claims are effective for that purpose. Thus, a claim reciting a dosage other than that in the cited patents is not obvious here under *In re Aller* because this dosage achieves an unexpected result and because no motivation to combine the cited documents is found.

C. Because the dosage range disclosed in the cited patents is insufficient for improving body weight uniformity, the skilled person would have no reasonable expectation of success in combining the cited documents.

Obviousness requires a reasonable expectation of success in combining known elements. *See* MPEP § 2143.02. As above, the dosages disclosed in the cited patents are insufficient to increase body weight uniformity. Thus one skilled in the art would have had no basis to practice the methods of the cited patents to increase body weight uniformity and would have had no expectation that those methods would increase body weight uniformity, regardless of dosage. The cited patents provide no basis for success even if combined with the safe higher dosages of Pimentel. Safety does not suggest efficacy for a previously unknown treatment. In addition, the higher dosage range recited in claim 29 led to unexpected results (improvement in body weight

uniformity). For these reasons, Applicants respectfully ask the Examiner to reconsider the obviousness rejections set forth in the Office Action dated December 19, 2007.

IV. NONSTATUTORY OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTIONS OVER U.S. PATENT NO. 6,213, 930 AND U.S. PATENT NO. 6,383,485

A. The Examiner's rejections.

The Examiner rejected claim 1, 5-10, 12, 25, 27, and 30-40 as being as being patentably indistinct from claims 1-11 of either U.S. Patent No. 6,213, 930 or U.S. Patent No. 6,383,485. Although the claims are not identical to the patented claims, the Examiner asserted that the patented claims anticipate the invention for the reasons of record, reiterating the arguments made in conjunction with the anticipation rejections above.

B. Because the present claims are patentably distinct from claims 1-11 of the cited patents, a double patenting rejection is improper.

As above, the claims at issue are not anticipated by U.S. Patent No. 6,213, 930 or U.S. Patent No. 6,383,485. In addition, it is not obvious that an agent that can enhance growth/feed behavior (U.S. Patent No. 6,213, 930) or reduce gastrointestinal inflammation (U.S. Patent No. 6,383,485) can improve body weight uniformity in a group of animals. This is especially true where, as here, the dosage claimed differs from the dosage disclosed in the cited patents. Accordingly, withdrawal of the non-statutory obviousness-type double patenting rejections is respectfully requested.

V. Nonstatutory obviousness-type double patenting rejections over both U.S. Patent No. 6,213, 930 and U.S. Patent No. 6,383,485 in view of Pimentel

A. The Examiner's rejections.

The Examiner rejected claim 29 for nonstatutory obviousness-type double patenting as obvious over claims 1-11 of either U.S. Patent No. 6,213, 930 or U.S. Patent No. 6,383,485 in view of Pimentel. The Examiner reiterated the arguments made in connection with the obviousness rejections discussed in section III above.

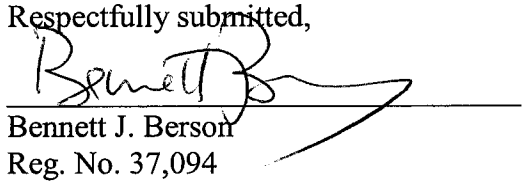
B. Claim 29 is not obvious over the cited documents because the claimed result is unexpected, and because the skilled person finds no suggestion or motivation to combine the cited documents and no indication of a reasonable likelihood of success in doing so.

The Applicants here repeat and incorporate the arguments presented in section III(2)-(3). The claimed dosage, which is outside the range of the dosages disclosed in the cited patents cannot be made obvious by including in the rejection another document (Pimentel) that discloses higher dosages to be safe, but does not disclose the claimed dosage to be sufficient to increase body weight uniformity. Accordingly, withdrawal of the nonstatutory obviousness-type double patenting rejection of Claim 29 is respectfully requested.

VI. SUMMARY

Having addressed each issue, Applicants believe that claims 1, 5-10, 12, 25, 27, and 29-40 are in condition for allowance and respectfully request a Notice of Allowance. Should any issues remain outstanding, the Examiner is invited to contact the undersigned at the telephone number appearing below if such would advance the prosecution of this application.

Respectfully submitted,



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